

### REMARKS

Applicants respectfully request reconsideration of the present case in view of the above amendments and the following remarks.

Claims 18, and 20-24 are currently pending. Claim 19 has been canceled. Claim 18 has been amended. Claims 23-24 have been added. No new matter has been inserted. The features of claim 19 were incorporated into claim 18. Claim 23 includes features from claims 18 and 21. Claim 24 includes features from claim 22.

### 35 U.S.C. § 103

#### Masalova, Papatheodoridis, Ling, and Schönbrunner

The rejection of claim 18 under 35 U.S.C. § 103(a) as unpatentable over Masalova et al., *J. Med. Virol.*, in view of Papatheodoridis et al., *J. Hepatol.*, and further in view of Ling et al., GB 2,051,357, and Schönbrunner, GB 2,313,666, was maintained. Applicants respectfully traverse this rejection.

While not conceding the correctness of the Examiner's position, in the interest of advancing prosecution, Applicants have inserted the features of dependent claim 19 into claim 18, rendering this rejection moot. Applicants respectfully request that this rejection be withdrawn.

#### Simmonds, Ling, and Schönbrunner

The rejection of claim 18 under 35 U.S.C. § 103(a) as being unpatentable over Simmonds et al., WO 93/10239, in view of Ling and Schönbrunner was maintained. Applicants respectfully traverse this rejection.

While not conceding the correctness of the Examiner's position, in the interest of advancing prosecution, Applicants have inserted the features of dependent claim 19 into claim 18, rendering this rejection moot. Applicants respectfully request that this rejection be withdrawn.

Masalova, Papatheodoridis, Simmonds, Ling, Schönbrunner, Lacroix, and Seidel

The prior rejection of claims 19-20 under 35 U.S.C. § 103(a) as being unpatentable over either of Masalova and Papatheodoridis, or of Simmonds, in view of Ling and Schönbrunner as applied to claim 18 above, and further in view of either Lacroix (EP 0507615) or Seidel et al., USPN 6,183,949, was maintained. Applicants respectfully traverse this rejection.

As a preliminary matter, Applicants note that the limitations of claim 19 were incorporated into claim 18. Therefore, the Examiner's arguments regarding claim 19 are assumed to apply against claim 18 and the following comments are drafted accordingly.

In response to the Examiner's rejection, Applicants assert that there is no motivation to combine the disclosures of Seidel or Lacroix with that of Masalova, Papatheodoridis, Simmonds, Ling, Schönbrunner. Specifically, Applicants point out that "the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. See *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990); MPEP § 2143.01. In this case, neither the disclosure of Seidel or Lacroix suggests the desirability of using antibodies for detection of HCV core antigen that "are selected from antibodies recognizing and binding to a region from position 100 to position 130 or from position 41 to 50 of HCV core antigen" in the context of a "a method for determining the presence of Hepatitis C virus (HCV) core antigen and anti-HCV core antibodies in a sample, at the same time, in the same vessel" as required by claim 18.

Further, Applicants point out that "at least some degree of predictability is required" to support an obviousness rejection. See MPEP § 2143.02; *In re Rinehart*, 531 F.2 1048 (C.C.P.A. 1976). In this case, both Seidel and Lacroix merely provide general disclosures of antibodies that could be made while failing to provide any reasonable degree of predictability that one of skill in the art could practice the invention claimed. Applicants point out that Seidel only generally states that "it is also possible using the peptide antigens according to the present invention to obtain antibodies by immunization methods familiar to one skilled in the art with which the virus itself can be detected in an immunological test." See col. 6. Yet, Seidel discloses no such actual antibodies. Further, Seidel provides no disclosure regarding antibodies that would be suitable for use in the context of a "a method for determining the presence of Hepatitis C virus (HCV) core antigen and anti-HCV core antibodies in a sample, at the same

time, in the same vessel" as required by claim 18. Therefore, Seidel does not provide the reasonable degree of predictability that is required to sustain this obviousness rejection.

Lacroix discloses that "the peptides of this invention, either free, polymerized or conjugated to an appropriate carrier are useful in eliciting antibodies". See p. 7. However, similar to Seidel, Lacroix discloses no such actual antibodies. Specifically, Seidel discloses no antibodies that would be suitable for use in the context of a "a method for determining the presence of Hepatitis C virus (HCV) core antigen and anti-HCV core antibodies in a sample, at the same time, in the same vessel" as required by claim 18. Therefore, Lacroix also does not provide the reasonable degree of predictability that is required to sustain this obviousness rejection.

For at least these reasons, the combination of Masalova and Papatheodoridis, or of Simmonds, in view of Ling and Schönbrunner, and further in view of either Lacroix or Seidel fails to teach or suggest the invention of claim 18. As claims 20-22 are dependent on claim 18, they are also not obvious. Applicants respectfully request that this rejection be withdrawn.

Masalova, Papatheodoridis, Simmonds, Ling, Schönbrunner, Cheng, and Khanna

The prior rejection of claims 21-22 under 35 U.S.C. 103(a) as being unpatentable over either of Masalova and Papatheodoridis or of Simmonds, in view of Ling and Schönbrunner as applied to claim 18 above, and further view of either of Cheng et al., US 5,627,080, or Khanna et al., US 5,032,503, was maintained. Applicants respectfully traverse this rejection.

The Examiner conceded that Masalova, Papatheodoridis, Simmonds, Ling and Schönbrunner fail to disclose "one or more detergents with one or more alkyl chains of at least 10 carbon atoms and one or more secondary to quaternary amines, or one or more non-ionic surfactants or both" as required by claims 21 and 23. Applicants assert that Cheng and Khanna fail to cure the deficiencies of Masalova, Papatheodoridis, Simmonds, Ling and Schönbrunner.

Cheng and Khanna show the use of detergents in the case of use as analytic-biotin bidentate reagent or in the case of decreasing complex formation. However, these uses are completely different from the use in the present invention. In addition, Cheng describes on column 7, lines 26 to 35, "the detergent(s) that may be employed in accordance with the methods

of the present invention include anionic detergents, cationic detergents(s), Zwitterionic detergents, and nonionic detergents." Therefore, Cheng provides no expectation of success because it merely provides a blanket disclosure of all kinds of detergents without identifying any in particular for use as claimed and without providing any expectation that any particular detergents would work with the invention as claimed.

In contrast, the present invention is directed to a method for determining the presence of HCV core antigen and HCV core antibodies at the same time in the same vessel. To successfully carry out such a specific method, claims 21 and 23 use detergents with one or more alkyl chains of at least 10 carbon atoms and one or more secondary to quaternary amines, or one or more non-ionic surfactants or both. Therefore, Applicants assert that the combination of Masalova, Papatheodoridis, Simmonds, Ling, Schönbrunner, Cheng and Khanna fails to render claims 21 and 23 obvious. As claim 22 is dependent on claim 21, and as claim 24 is dependent on claim 23, they are also not rendered obvious. Applicants respectfully request that this rejection be withdrawn.

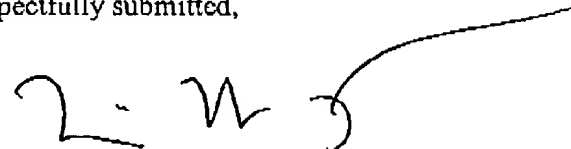
#### Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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Date

  
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